

DOCKET NO.: TJU-2290

PATENT

GP 1642  
#4/42  
7/04/98

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman

Serial No.: 09/046,178

Group Art Unit: 1642

Filing Date: March 23, 1998

Examiner: T. Scheiner

For: METHODS OF AND KITS AND COMPOSITIONS FOR DIAGNOSING  
COLORECTAL TUMORS AND METASTASIS THEREOF

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Date of deposit: June 22, 1998  
I hereby certify that this paper is being deposited with the United States Postal Service as First Class Mail, postage prepaid on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

Mark DeLuca  
Typed Name: Mark DeLuca  
Registration No.: 33,229

Assistant Commissioner for Patents  
Washington DC 20231

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

- ☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- ☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐the first or ☐second After Final Submission, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$240.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$240.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).
- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☒ In view of the voluminous nature of references **AD, CL, and CO**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

- ☒ In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:
- ☒ Copies of references **AA through AC, AE through CK, CM, CN, CP, and DC through DJ**, listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/305,056**, filed **September 13, 1994**. Copies of references **CQ and DB** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. **08/789,270**, filed **January 29, 1997**.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

### INFORMATION

Applicant has learned that ST receptor-encoding mRNA has been detected by PCR in whole blood samples from individuals who do not have metastasized colorectal tumors. Using quantitative PCR, Applicant has determined that the number of copies of such ST receptor-encoding mRNA-specific in whole blood samples from individuals who do not have metastasized colorectal tumors to be approximately 1 copy of mRNA per 1,000-10,000 nucleated cells. No ST receptor protein has been detected in whole blood samples from individuals who do not have metastasized colorectal tumors.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date:

June 22 1998



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